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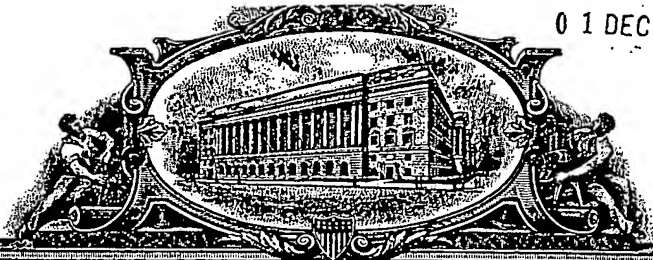
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# THE UNITED STATES OF AMERICA

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APPLICATION NUMBER: 60/154,215

FILING DATE: September 16, 1999

## PRIORITY DOCUMENT

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COMMISSIONER OF PATENTS AND TRADEMARKS

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

The Commissioner of Patents & Trademarks, Washington, D.C. 20231, U.S.A.

The attached application is a provisional application for patent under 37 C.F.R. §1.53(b)(2).

Inventor(s) name(s): (1) SONYA MONGOMERY, Mississauga, Ontario, Canada (2) ALLEN MUIRHEAD, Mississauga, Ontario, Canada (3) MURRAY VOAKES, Mississauga, Ontario, Canada (4) PAUL MOORE, Mississauga, Ontario, Canada (5) TARAS WORONA, Mississauga, Ontario, Canada (6) SIMON TREADWELL, Mississauga, Ontario, Canada

Title of the Invention: METHOD AND APPARATUS FOR TREATING BLOOD

The names and registration numbers of the attorneys for this provisional application for patent are:

Ingrid E. Schmidt, Registration No. 33,344  
Christopher R. Scott, Registration No. 26,058  
Robert F. Delbridge, Registration No. 24,969

Rogers & Scott File Number: 6823-US

This provisional application contains:


1. ....4..... pages of specification
2. ....2..... sheets of drawings (depicting Figures ....1... - ....2...)
3. .... Assignment (s) of the Invention
4. ....3..... Entity Status Declaration (s)

Please charge our Deposit Account No. 18-1840 in the amount of \$ 75.00

The Commissioner is hereby authorized to charge any additional fees, except issue fees, which may be required at any time during prosecution of this application without specific authorization, or credit any overpayment to Deposit Account No. 18-1840.

TWO copies of this sheet are enclosed for accounting purposes.

September 15, 1999  
Date

  
Attorney of Record Robert F. Delbridge  
Registration No. 24,969

Applicant or Patentee: SONYA MONTGOMERY ET AL  
Serial or Patent No.: --  
Filed or Issued: Being filed herewith  
Title: METHOD AND APPARATUS FOR TREATING BLOOD

Attorney's  
Docket No.: 6823-US

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(a))-SMALL BUSINESS CONCERN

I hereby declare that I am

- ☐ the owner of the small business concern identified below:  
☒ an official of the small business concern empowered to act on behalf of the concern identified below

NAME OF SMALL BUSINESS CONCERN VASOGEN INC.  
ADDRESS OF SMALL BUSINESS CONCERN 2155 Dunwin Drive, Suite 10,  
Mississauga, Ontario, Canada L5L 4M1

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121 for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled METHOD AND APPARATUS FOR TREATING BLOOD by inventor(s) SONYA MONTGOMERY; ALLEN MUIRHEAD; MURRAY VOAKES; PAUL MOORE; TARAS WORONA; SIMON TREADWELL described in

- ☒ the specification filed herewith.  
☐ application serial number \_\_\_\_\_, filed \_\_\_\_\_  
☐ patent number \_\_\_\_\_, issued \_\_\_\_\_

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e). \*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Paul G. A. Moore  
TITLE OF PERSON IF OTHER THAN OWNER Executive Vice-President & COO  
ADDRESS OF PERSON SIGNING 2155 Dunwin Drive, Suite 10, Mississauga, Ontario, Canada  
L5L 4M1  
SIGNATURE G. R. D. Duffin (24,960) DATE Sept 15, 90

Applicant or Patentee: SONYA MONGOMERY ET AL  
Serial or Patent No.: ---  
Filed or Issued: Being filed herewith  
Title: METHOD AND APPARATUS FOR TREATING BLOOD

Attorney's  
Docket No.: 6823-US

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(b))-INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office regarding the invention entitled METHOD AND APPARATUS FOR TREATING BLOOD described in:

- ☒ the specification filed herewith.  
☐ application serial number \_\_\_\_\_, filed \_\_\_\_\_  
☐ patent number \_\_\_\_\_, issued \_\_\_\_\_

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:\*

- ☐ No such person concern, or organization  
☒ Persons, concerns or organizations listed below\*

\* Note: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME VASOGEN INC.  
ADDRESS 2155 Dunwin Drive, Suite 10, Mississauga, Ontario Canada L5L 4M1  
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NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

SONYA MONGOMERY  
NAME OF INVENTOR  
[Signature]  
Signature of inventor  
September 15, 1999  
Date

ALLEN MUIRHEAD  
NAME OF INVENTOR  
[Signature]  
Signature of inventor  
September 15, 1999  
Date

MURRAY VOAKES  
NAME OF INVENTOR  
[Signature]  
Signature of inventor  
September 15, 1999  
Date

Applicant or Patentee: SONYA MONGOMERY ET AL  
Serial or Patent No.: --  
Filed or Issued: Being filed herewith  
Title: METHOD AND APPARATUS FOR TREATING BLOOD

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☐ patent number \_\_\_\_\_, issued \_\_\_\_\_

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PAUL MOORE  
NAME OF INVENTOR  
[Signature]  
Signature of inventor  
September 15, 1999  
Date

TARAS WORONA  
NAME OF INVENTOR  
[Signature]  
Signature of inventor  
September 15, 1999  
Date

SIMON TREADWELL  
NAME OF INVENTOR  
[Signature]  
Signature of inventor  
September 15, 1999  
Date

## Provisional Patent Disclosure

### 1.0 General Description of the Product and What the Patentable Areas Are.

The Blood Container (BC) VC7102 is a container that is meant to work in concert with the Vasogen VC7101 Blood Treatment unit (BTU). The blood container holds the blood in a manner that allows the stressors of the BTU to penetrate the container while keeping the blood within the container to prevent any biohazardous conditions from arising. The blood container will interface with the BTU as required to carry out the stressor delivery. The stressors to be delivered to the blood located in the BC are heat from an infrared lamp, Ozone from a gas source and Ultraviolet (UVC) radiation from UV lamps. The BC is connected with syringes to facilitate the blood removal from the patient, the Blood insertion into the BC and the blood removal from the BC in a closed system to prevent the risk of blood contamination of the clinician and BTU. Many of the operator interventions and bio-hazardous exposure, of the previous system, have been mitigated by automation. This results in a closed system for handling the blood that prevents the operator from being contaminated and delivers a syringe of treated, degassed blood ready for re-injection into a patient.

The patentable areas as we see them are:

- 1.1 Use of a smart card to match patient to disposable and to record the lot number of the disposable for input into the machine, as well as the possibility of using it as a pay-per-treatment means. (The old system used labelled stickers to attach to the patient, the bottle and the patient record. The new system saves time in the keying in of patient numbers and helps to prevent mixing blood between patients)
- 1.2 Use of a closed system of tubing to input the blood into the bottle reducing the level of bio-hazardous exposure. (Previously there were a number of opportunities to spill and spatter blood on the operator and the machine, an accessory was even developed to prevent spillage on the machine and this new system no longer requires the accessory.)
- 1.3 The closed system in conjunction with a tube heat sealing and cutting device. (This allows the tethered, blood-contaminated tubing to be cut from the BC and discarded safely. Furthermore, it provides an automatic cap on the output syringe where one had to be put in place by the operator before.)
- 1.4 Delivery of pre-loaded and degassed treated blood syringe with a sealed cap (see 1.3). (Previously nurses were required to fill the syringe manually then attempt to degass the blood manually by knocking it onto a hard surface to break the gas bubbles. This took a lot of time and the results were subjective. The cap on the syringe would be manually put on after the syringe was disconnected from the BC, creating a potential biohazard.)
- 1.5 A new disposable that automatically connects with the machine for the ozone and thermocouple connections. (Previously the bottle was input into the machine and three separate connections were required to be made. These were ozone-in tubing, ozone-out tubing and the thermal sensor

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plug.

- 1.6 Packaging accessory to manage the length of tubing. Extra long tubing is needed for the closed system and the accessory is used to manage that so that the operator can easily handle the tubing.
- 1.7 The use of a touchscreen display rather than a computer keyboard.
- 1.8 The use of an on-board printer to record the information of the treatment, the patient, the operator, the lot number of the disposable and the date and time. (Previously, a full-page printout was provided and the info. was keyed manually into the computer. Most of the info. is now retrieved by the machine using the smart cards.)
- 1.9 The use of a cart to hold the machine with locking wheels. The cart also has a shelf that pulls out to provide a working surface for the operator. The cart will also have drawers to store disposables.

2.2 Clinical Procedure: See Figs. 1 & 2

The BC package is opened and a patient smart card is removed. That smart card is the identification of the BC lot number and is a unique treatment identifier that is used to identify the patient after the treatment is complete to ensure that the blood from another patient is not accidentally inserted into the patient.

The smart card of the operator and the treatment (doubles as a patient identifier) is inserted into the machine to open the BTU door.

The BC is removed from the packaging and is inserted into the BTU. The BC connects to the BTU with gas connections, electrical connections for the thermal sensor and is latched in place to prevent removal during treatment. The connections and latching are made automatically when the BC is inserted into the BTU. The output syringe, attached to the BC, is inserted into the syringe actuator located on the BTU. The input syringe is connected to the BC via a three-way stopcock. The stopcock connections lead to the input syringe, a tube leading to the BC and syringe needle. A packaging assistant is shipped with the BC to ensure that the syringes and tubing are manageable when being handled by an operator.

The needle on the stopcock punctures a bag of sodium citrate and the input syringe is actuated until a quantity of sodium citrate is withdrawn into the syringe. The needle is withdrawn from the citrate bag. The needle on the stopcock is discarded and the syringe is placed on a working surface. The tubing extension of a butterfly needle is attached to the stopcock where the needle



once was.

The butterfly needle is inserted into the patient's vein and taped in place. A quantity of blood is drawn into the syringe and gently mixed with the sodium citrate. The blood and sodium citrate mixture is targeted to be 10 parts blood versus 3 parts sodium citrate by volume and is required to prevent coagulation. The stopcock is then set to point into the BC and the blood is injected into the BC by actuating the syringe plunger by hand. The input array of tubing to the BC is heat sealed and severed near the BC (At HS2, see drawing). The input butterfly needle is removed from the patient and the entire array of butterfly needle; input syringe, stopcock and extension tube is discarded.

The machine treats the blood by heating, injecting with ozone gas and then irradiating with UVC radiation. The temperature of the blood is controlled using a temperature sensor. The treatment ends.

The output syringe is activated by the syringe actuator and is filled with the treated blood by drawing the blood from the blood pool at the base of the BC. The blood is degassed by clamping the output tubing and actuating the syringe open further creating a vacuum. The syringe is vibrated slightly to promote bubble collapse. The clamp is then released and the excess gas in the syringe is pushed back into the BC by actuating the output syringe closed slightly. The output tubing is heat-sealed and severed near the top of the syringe (at HS1), a cap for the syringe is formed. The clinician removes the sealed syringe from the machine for re-insertion into a patient.

The patient is then re-injected with the treated blood under anaesthetic. To do this the Patient is anaesthetized using a needle in the Gluteus maximus muscle. The Anaesthetic syringe is removed and the needle is left in the patient. The Blood output syringe is taken and the cap formed by the heat sealing is removed and discarded. The blood filled syringe is attached to the needle located in the patient and the blood is injected into the patient over a 60-second period. The syringe and needle are removed from the patient and then discarded.

The clinician removes the BC from the unit and discards it when the patient is not present.

- 2.3 Details on the interface of the machine with the operator and the handling of the smart cards are shown below in a story board for the video to be filmed.

#### Sequence of Actions

A- indicates actions, S- indicates screen shot of machine video display with text writing

- A1 \*\* this space intentionally left blank \*\*
- A2 \*\* this space intentionally left blank \*\*
- S3 "Please insert operator card and insert PIN number"
- A4 operator installs card and punches in pin number onto screen.
- S5 "Please insert patient matching card"
- A6 Patient matching card inserted into the machine, and the door to the machine opens.
- S7 "Please install blood container and close door."
- A8 Show the blood container being placed into the machine and the output syringe being loaded into the machine.  
Show the packaging assistant being removed from the input syringe and discarded.  
Show the citrate being placed into the syringe.  
Show the blood being removed from the patient and the gentle mixing of the citrate and blood.  
Show the stopcock being thrown and the air being drawn into the syringe.  
Show the syringe being inverted and the blood being input into the BC.  
Show the door being closed.
- S9 "Please Remove the patient card and affix to the patient" (card has a clip on it to fix to patient)

A10 Show patient card being removed  
 S11 "Input tube being heat sealed"  
 S12 "Please remove operator card and withdraw Phlebotomy set from the machine"  
 A13 Operator card being removed and phlebotomy set removed from the machine and the patient; Entire set discarded.  
 S13 "System locked, Blood being processed" time bar at 0 time, "time remaining: XX min"(30 pt)  
 S14 "System locked; Blood being processed" time bar at 1/3 time, "time remaining: XX min"(30 pt)  
 S15 "System locked, Blood being processed" time bar at 2/3 time, "time remaining: XX min"(30 pt)  
 S16 "System locked, Blood being processed" time bar at 1 time, "time remaining: XX min"(30 pt)  
 A17 patient and operator come back to machine  
 S18 "Insert operator card and patient card to fill output syringe"  
 A20 Show operator removing the card from the patient and inserting into the machine. Show operator inputting operator card. Show operator entering the pin number  
 S21 "Output syringe being filled"  
 A22 Machine door pops open.  
 S22 "Please remove patient card and affix to patient, remove output syringe with treated blood, remove print out for patient records"  
 A23 Operator removes patient card and attaches to patient. Operator removes syringe and takes patient away to treatment room. Operator removes printout and puts into patient file  
 S24 "Remove Blood container from the machine and lock the door"  
 A25 Operator removes blood container from the machine and locks the door; disposes of container.  
 S26 "Please remove operator card"  
 A27 Operator removes card and walks away  
 Operator settles patient onto treatment bed.  
 Operator drapes patient with treatment drape.  
 Operator wipes gluteus maximums of patient with alcohol.  
 Operator assembles syringe with cannula and fills syringe with novocaine.  
 Operator inserts syringe into patient and administers novocaine.  
 Operator twists off syringe from needle and discards.  
 Operator obtains blood syringe and removes cap.  
 Operator twists blood syringe onto needle and begins to re-inject blood into patient.

FIN

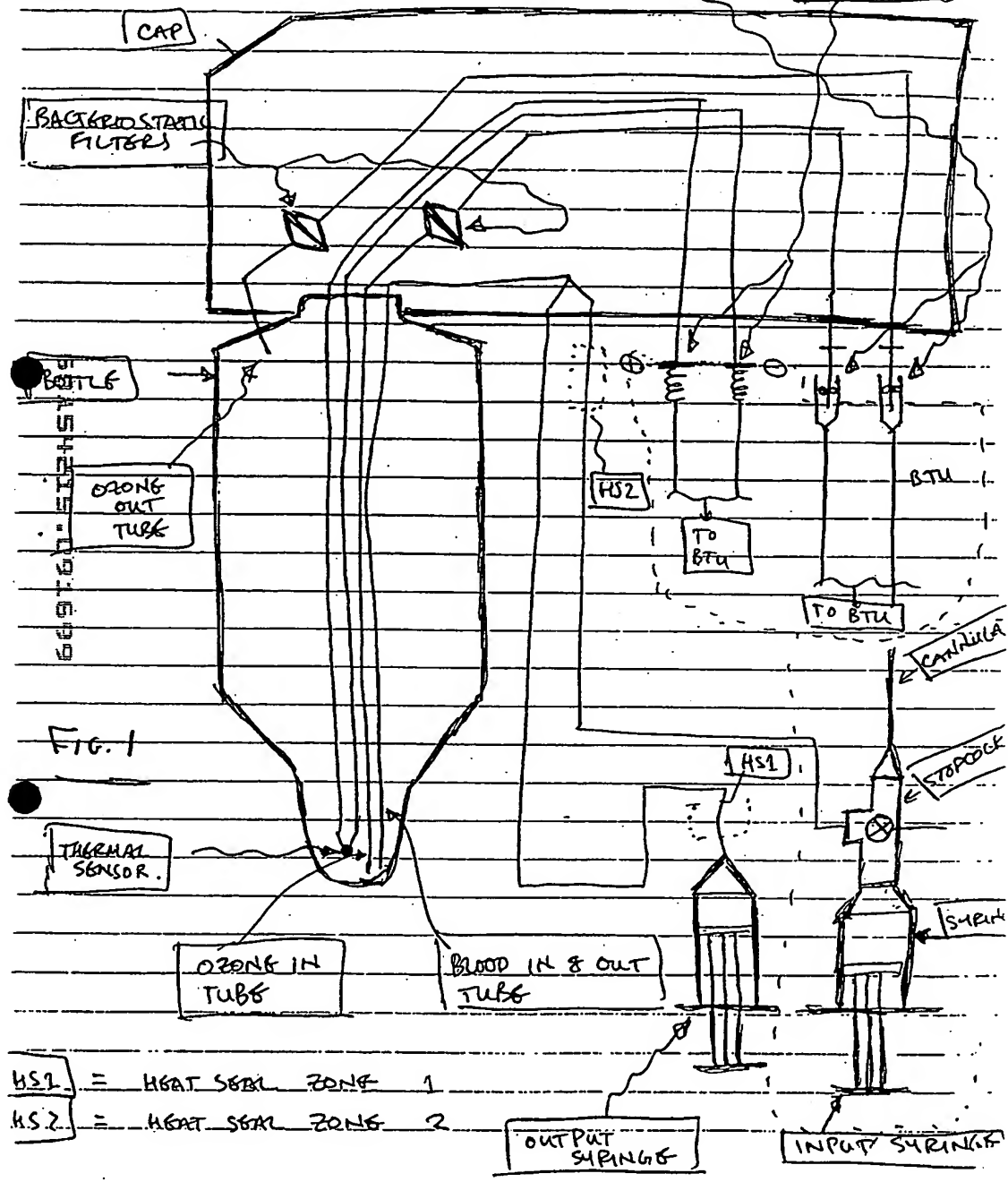
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**SCHEMATIC OF GAS  
LIQUID & ELECTRICAL  
CONNECTIONS**

**OZONE  
GAS FITTINGS**

**ELECTRIC  
SPRING  
CONTACTS**

99-09-14



HS1 = HEAT SEAL ZONE 1  
HS2 = HEAT SEAL ZONE 2

**OUTPUT  
SPRING**

**INPUT  
SPRING**

99-09-14

